

REMARKS**I. Status of the Claims.**

Claims 1-8 are withdrawn.

Claims 10, 13 and 16 are cancelled.

Claims 18-20 are added.

Claims 9, 11-12, 14-15 and 17 are under examination.

II. Crawford Does Not Anticipate Amended Claim 9.

Amended claim 9 and claims dependent on it (11, 14-15) are not anticipated by Crawford.

Crawford teaches an anti-inflammatory composition. Piroxicam is essential. Analgesics listed in the composition are acetaminophen, antidepressant doxepin, bronchodilator pirbuterol, minor tranquilizer diazepam, or antihypertensive agent trimoyosin. Crawford's goal was an improved anti-inflammatory composition that reduced gastrointestinal (GI) irritation. Large amounts of ingredients are in his teachings as optionally in a composition - these are not within the scope of "consisting essentially of" of the present invention, which does not include all these compounds, and whose goal is pain relief, not to reduce GI irritation. "Consisting essentially of" should include materials specified in the claim "and those that do not materially affect the basic and novel characteristics of the claimed invention." (see MPEP 2111.03). Applicant believes this definition excludes the piroxicam, and analgesics of Crawford. Those of skill in the art would **not** consider teachings of Crawford when searching for a pain relief medication because no data is presented in Crawford regarding pain or pain relief.

The examiner discounted applicant's argument that the present composition is directed toward pain relief. Whereas the examiner agrees, Crawford's goal is to reduce GI irritation, he discounted the preamble as not having patentable weight.

Applicant's argument is not just that a preamble should be accounted patentable weight, but that those of skill in the art seeking a pain relief composition, would not be directed to Crawford who does not even mention pain. This publication would not appear in a "pain" literature search.

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the

balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). The stated goal of the disclosure is pain relief so the preamble fulfills the criteria in the court decision.

Although claims at issue are to a composition not a method, all case law indicates the preamble relates to the claim interpretation.

See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333-34, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003) (In a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the preamble is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. Thus the claim is properly interpreted to mean that the vitamin preparation must be administered to a human with a recognized need to treat or prevent pernicious anemia.); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) (A claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates")).

Also, because of the large number of analgesics listed with piroxicam, there is no guidance to the present claimed composition.

Dose range of the tricyclic anti-depressant of claim 9 is not in Crawford, nor does the Examiner allege teaching the claimed dose range. The examiner admits that Crawford et al. teaches piroxicom with doxepin, although separately administered and that "Crawford et al. does not specifically teach that the compositions as exemplified comprise a standard dose and a low dose" in the Office Action mailed January 28, 2009, at p. 16. Therefore, at least one claimed element is not taught in Crawford so it cannot anticipate.

III. A Prima Facie Case of Obviousness Is Not Established.

Claims 12 and 17 were rejected over Crawford, with Caruso and with Matheson.

An improvement of the lower tricyclic antidepressant doses claimed herein is to eliminate side effects, notably sedation and anticholinergic side effects such as dry mouth, blurred vision and urinary retention.

Caruso teaches only an antidepressant, the invention presented to those of skill in the art is

effectiveness of an antidepressant is significantly potentiated by administering the antidepressant prior to, with or following the administration of a nontoxic NMDA receptor antagonist.

for alleviation of “neuropathic pain.” (Caruso, Abstract and p. 1). To alleviate this level of pain, much higher doses than claimed herein, are necessary.

Unless “a nontoxic NMDA receptor antagonist” as defined on p.1, lines 19-24, is the same as a “non-narcotic analgesic” in present claim 9 from which claim 17 depends, Caruso’s contribution to an obviousness rejection is at most providing an “antidepressant.” Examples of non-narcotic analgesics in the present application are acetaminophen and NSAIDs (e.g., aspirin, ibuprofen, flurbiprofen, ketoprofen, and naproxen).

It would be clear to those of skill in the art that what Caruso **teaches** is a composition of

- antidepressant plus
- non-toxic NMDA receptor antagonist.

The entire thrust of the invention is these two components, as set forth in claim 9 as amended. The teaching is that in combination they improve pain relief. The entire Summary, and the first three pages of the Description of the Preferred Embodiments must be read until page 7, lines 10-24 referred to by the Examiner, in which a laundry list of “optionally” included “pharmacologically active substances” appears – over 50 (fifty) of such substances are listed. In the laundry list there is a category “non-narcotic analgesics” – the second component of the two part composition of the present claims, but there is no guidance to select one of the multiple optional categories, nor any discussion of what they would add to the effects of Caruso’s invention that would teach one of skill in the art to make a composition **including** an **optional** component of Caruso’s composition and **excluding** an **essential** compound.

Doses (325 mg) of some non-narcotic analgesics are only provided for these optional ingredients within a table format called “Examples 1-46”. These must be in combination with not only an antidepressant, but also a non-toxic NMDA receptor antagonist. This is not teaching the present claims. One of skill in the art would not be led to tease out of a laundry list, the combination presently claimed. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a “laundry list” disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not “reasonably lead” those skilled in the art to any particular species).

Matheson does not substitute for deficiencies in Crawford with Caruso. Matheson only described rofecoxib. Matheson and Figgitt is simply a review of Rofecoxib, a (COX)-2 inhibitor. It really stretches the imagination to postulate how those of skill would combine this publication with Crawford, and in doing so come up with the claimed invention. A determination of obviousness requires that “the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” *KSR International Co. v. Teleflex, Inc.*, — U.S. —, 127 S.Ct. 1727, 1734, 82 U.S.P.Q.2d 1385 (2007) quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). In making a determination of obviousness by looking at the teachings of multiple patents, one should consider

the effects of demands known to the design community or present in the market place; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be **made explicit**.

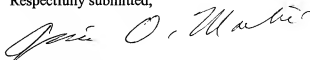
KSR, 127 S.Ct. at 1740-41 (*emphasis added*). “[A] patent composed of several elements is not proved obvious merely by demonstrating the each of its elements was, independently, known in the prior art.” *Id.* at 1741. Since this is all the examiner has done in the present case, please withdraw this rejection.

IV. Other Issues.

Applicant thanks the Examiner for withdrawing previous rejections under 112 and 102 (Caruso, Kakuyoma). We conferred with the Examiner during a telephone conversation on September 14, 2009, and confirmed that although not so designated in the Office Action, this was a Final Rejection.

For the reasons stated herein, please allow all pending claims. No other fees are believed due at this time, however, please charge any additional deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (41957-102748).

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Alice O. Martin", written in dark ink.

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